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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,455	04/05/2005	Alexander Von Weymarn-Scharli	A013-5480 (PCT)	2990
40627	7590	11/14/2007		
ADAMS & WILKS 17 BATTERY PLACE SUITE 1231 NEW YORK, NY 10004			EXAMINER EISEMAN, ADAM JARED	
			ART UNIT 4153	PAPER NUMBER
			MAIL DATE 11/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,455

Applicant(s)WEYMARN-SCHARLI,
ALEXANDER VON**Examiner**

Adam J. Eiseman

Art Unit

4153

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/530,455, filed on August 19, 2003.
2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.

Art Unit: 4153

- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION. •
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

5. The title of the invention is not descriptive of the disclosed invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following titles are suggested: "Controllable Stiffness Catheter Guide Device" or similar titles better describing the variable and controllable stiffness of the guide device.

6. The disclosure is objected to because of the following informalities: Claim language in abstract, lack of properly labeled sections of specification as listed in the arrangement of specification section, and title not effectively describing invention.

Appropriate correction is required.

Claim Objections

7. Claims 12-19 are objected to because of the following informalities: Claims 12-19 are dependant claims, which the examiner recognizes as being dependent on claim

Art Unit: 4153

11. However, they are currently written as "a guide device according to claim 1" instead of correctly referring to claim 11. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim in view of the specifications does not provide description as to how the applicant intends to ensure that the wires lie flat against each other in response to the application of magnetic fields.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 11-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danforth (US Patent 4822345).

Danforth discloses a controllable flexibility catheter, which allows the operator of the catheter to adjust the flexibility/stiffness of the catheter while it is inserted. The catheter is described as to control the rigidity of the catheter by inflating and deflating a balloon inside the catheter (abstract). It is also disclosed in Danforth'345 that another embodiment of the invention would include the catheter is fabricated from material having properties which change when subjected to magnetic fields or penetrating forces such as electric current. These magnetic fields or electric currents are employed to increase the rigidity of the catheter (column 7, lines 31-37).

Regarding claim 11, Danforth does not specifically disclose the use of first and second wire(s) connected by a control device, which are mutually attracted at will to control the relative movement between the wires. However, it would be obvious to one of ordinary skill in the pertinent art at the time of invention to use magnetic fields and electric current to increase and decrease rigidity of a catheter based on the Danforth'345 disclosure of use of guide device fabricated from material having properties that change when subjected to magnetic fields or electrical current (column 7, lines 31-37). Note that the examiner interprets "relative movement between the wires" as a measure of stiffness or rigidity as implied in the specification. Thus it would be obvious to use materials which when subjected to magnetic fields or electric current changes would change the rigidity of the guide device, as taught by Danforth, including mutual

Art Unit: 4153

attraction of wires brought on by some control device to dictate the stiffness of a guide device as described in claim 11.

Regarding claims 12 and 13, as disclosed in Danforth, a guide catheter can be made from a material with properties that change when subjected to magnetic fields or electrical current (column 7, lines 31-37); thusly including magnetized material, fluids or coatings.

Regarding claim 14, Danforth further discloses the use of magnetic fields and electrical voltage to change properties of a catheter guide device (column 7, lines 31-37).

13. Claim 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Danforth in view of Voelker (German Patent DE100017147) and Ehr (US Patent 5706827).

Regarding claim 15, Danforth discloses the use of magnetic fields and/or electrical voltage to increase or decrease the rigidity of a guide device while Voelker and Ehr disclose the arrangement of a wires in a guide device as beside each other as well as parallel (Ehr figure 6) and concentrically (Voelker paragraph 5). Thus it would be obvious to substitute the Ehr and Voelker wire configurations with Danforth's method of controlling guide device flexibility.

Regarding claim 17, it is an inherent property of magnets or magnetized materials that when flat wires are magnetized they will lie flat against each other.

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Danforth in view of Inagaki (US Patent 5630806).

Regarding claim 16, Danforth discloses the use of magnetic fields and/or electric voltage to control the stiffness of a guide device. Inagaki discloses mean of reinforcing medical tubing by wrapping with the tubing with one or more strands at equal distances between each strand (column 3, lines 25-28). It would have been obvious to one of ordinary skill in the art incorporate Inagaki's idea of wrapping strands of wire around medical tubing, such as a catheter, into Danforth's concept of controllable stiffness of a catheter through magnetic fields or electric voltage. Danforth's concept of controllable stiffness through magnetic or electrical means could have been used to differ wrapping strand spacing which in turn determines tubing flexibility (column 2, lines 38-61). Inagaki discloses the changing of strand spacing as a means for controlling rigidity of the tubing (column 2, lines 38-61).

15. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danforth in view of Bauerfeind (US Patent 5337733), Voelker and Ehr.

Bauerfeind discloses a tubular inserting device with variable rigidity that consists of a tubular device consisting of an inner wall and outer wall with an intermittent space between the walls. Fluid under pressure is introduced and removed from the intermittent space in order to move the walls toward and away from each other (column 3 lines 34-66). The goal is controlling the flexibility of a device within the inner tube by putting pressure on said device from the inner tube (column 3, lines 50-66). As reported above, Voelker and Ehr disclose ways of aligning threads as concentric and parallel respectively; and Danforth discloses the use of employing magnetic fields or electrical

Art Unit: 4153

voltage to control the rigidity of a guide device through changing the properties of the guide device.

Regarding claims 19 and 20, it would be obvious to someone of ordinary skill in the pertinent art of controlling the flexibility of a guide device to incorporate Bauerfiend technique of separating and attaching the walls of a guide device through introduction and removal of fluid under pressure as a way of separating and allowing for attraction the threads as described in Voelker and Ehr that are magnetized or have current running through them as described by Danforth.

Allowable Subject Matter

16. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 18 utilized permanent alternatively generated magnetic fields along the length of the thread and is novel as other prior art relies on employing a magnetic field or electric voltage to control the stiffness or uses permanent magnets in order to stabilize a guide or catheter rather than vary the flexibility.

Conclusion

The prior art made of record but nor relied upon and considered pertinent to the applicant's disclosure.

US Patent 5269759 by Hernandez, which discloses a magnetic guidewire coupling which uses a plurality of magnets to stabilize and extend a catheter.

Art Unit: 4153

US Patent 5813996 by St. Germain, which discloses a guide wire extension system with magnetic coupling.

US Patent 6002184 by Delson, which discloses an actuator with opposing repulsive magnetic forces which can be used to control stiffness of a device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam J. Eiseman whose telephone number is (571) 270-3818. The examiner can normally be reached on Mon-Thurs, 8:00 PM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. J. E./ AE
10/31/2007

GARY JACKSON
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink, appearing to read "Gary Jack", written over a horizontal line.